

200.1133CON2

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner:	Not Yet Assigned	Art Unit:	
Re:	Application of:	Benjamin OSHLACK, et al.	
Serial No.:		Not Yet Assigned	
Filed:		Herewith	
For:		TAMPER-RESISTANT ORAL OPIOID AGONIST FORMULATIONS	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 4, 2003

S i r:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Forms PTO-1449, which is a copy of the Forms submitted in connection with the parent application, US Serial No. 09/781,08, for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants also respectfully advise the Examiner of the following issued U.S. patents and co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 10/244,783, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed September 16, 2002, which is a continuation application of U.S. Patent Application Serial No. 09/815,167, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed March 22, 2001, now U.S. Patent No. 6,475,494, issued on November 5, 2002, which is a continuation application of U.S. Patent Application Serial No. 09/218,662,

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

200.1133CON2

"OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed December 22, 1998, now U.S. Patent No. 6,277,384, issued on August 21, 2001.

U.S. Patent Application Serial No. 09/992,936, "OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS", filed November 5, 2001, which is a continuation application of U.S. Patent Application Serial No. 09/503,020, "OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS", filed February 11, 2002, now U.S. Patent No. 6,375,957, issued on April 23, 2002, which is a continuation-in-part of U.S. Patent Application Serial No. 09/218,662, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed December 22, 1998, now U.S. Patent No. 6,277,384, issued on August 21, 2001.

U.S. Patent Application Serial No. 09/815,162, "METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS", filed March 22, 2001, which is a continuation application of U.S. Patent Application Serial No. 09/218,663, "METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS", filed December 22, 1998, now U.S. Patent No. 6,228,863, issued on May 8, 2001.

U.S. Patent Application Serial No. 09/781,076, "CONTROLLED-RELEASE COMPOSITIONS CONTAINING OPIOID AGONIST AND ANTAGONIST", filed February 8, 2001, pending.

U.S. Patent Application Serial No. 10/199,972, "PHARMACEUTICAL COMBINATIONS OF OXYCODONE AND NALOXONE", filed July 18, 2002, pending.

U.S. Patent Application Serial No. 10/213,919, "OPIOID AGONIST FORMULATIONS WITH RELEASABLE AND SEQUESTERED ANTAGONIST", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,408, "SEQUESTERED ANTAGONIST FORMULATIONS", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/213,921, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND BITTERING AGENT", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,409, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST, AND IRRITANT", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,413, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND GELLING AGENT", filed August 6, 2002, pending.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii) the Examiner's attention is directed to Exhibit A attached herewith which contains the following:

(i) specifications and claims for pending application serial nos. 09/781,076; 10/199,972; 10/213,919; 10/214,408; and 10/213,921;

(ii) claims of pending application serial no. 10/244,783, which has the same specification as U.S. Patent No. 6,277,384, listed as reference AB on the Form PTO 1449 submitted with the Information Disclosure Statement of November 7, 2001;

(iii) claims of pending application serial no. 09/992,936, which has the same specification as U.S. Patent No. 6,375,957, listed as reference LD on enclosed Form PTO-1449;

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

(iv) claims of pending application serial no. 09/815,162, which has the same specification as U.S. Patent No. 6,228,863, listed as reference AA on the Form PTO 1449 submitted with the Information Disclosure Statement of November 7, 2001;

(v) claims of pending application serial nos. 10/214,413; and 10/214,409, which have the same specification as that of application serial no. 10/213,921, mentioned above in paragraph (i).

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any additional fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso
Reg. No. 41,240

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081									
LIST OF PRIOR ART CITED BY APPLICANT				APPLICANT(S): Oshlack, et al		FILING DATE: February 8, 2001									
(Use several sheets if necessary)															
U.S. PATENT DOCUMENTS															
*EXAMINER INITIAL		DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		AA	3	0	0	5	2	0	0						
	AA	3	0	0	5	2	0	0	06/22/1976	Leslie	424	22			
	AB	4	2	3	1	1	4	0	12/02/1980	Dudzinski	424	290			
	AI	4	3	0	5	3	1	0	12/28/1982	Leslie	536	56			
	AD	4	4	4	3	4	2	0	04/17/1984	Oshlack, et al.	424	22			
	AE	4	0	2	8	0	3	0	05/09/1989	Elger, et al.	424	486			
	AF	4	8	3	4	0	8	5	05/30/1989	Martani, et al.	424	488			
	AI	4	4	3	1	1	4	4	05/30/1989	Goldie, et al.	424	488			
	AI	4	4	3	1	3	0	5	05/30/1989	Elger, et al.	424	488			
	AI	4	4	4	4	0	0	2	07/04/1989	Elger, et al.	424	485			
	AI	4	4	4	4	0	0	9	07/04/1989	Goldie, et al.	424	480			
FOREIGN PATENT DOCUMENTS															
		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
		AD	0	1	0	3	3	0	0					YES	NO
	AD	0	1	0	3	3	0	0	09/03/1986	Europe (A3)	A61K	31/615			
	AL	0	3	4	3	2	4	3	06/07/1989	Europe (A1)	A61K	31/485			
	AI	0	3	2	0	9	4	3	11/07/1990	Europe (A2)	A61K	31/485			
	AN	0	0	0	1	3	4	7	01/13/2000	WO	A61K	31/00			
	AD	0	0	0	1	9	0	0	05/17/1990	WO	A61K	31/485			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
	AP	Translation of previously submitted German patent application DE 43 25 465													
	AQ	Alvarez-Fuentes, et al., "Effectiveness of Repeated Administration of a New Oral Naltrexone Controlled-Release System on Morphine Analgesia", J. Pharm Pharmacol (2001), 53; pg. 1201-1205													
	AR	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice", J. Pharm Pharmacol (2000), 52; pg. 659-663													
EXAMINER James Alstrum Acevedo/											DATE CONSIDERED 06/08/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.															

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. //J.H.A.A./

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT				APPLICANT(S): Oshlack, et al.									
(Use several sheets if necessary)													
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		DOCUMENT NUMBER			DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
	CA	4	8	6	7	2	8	6	09/19/1989	Heafield, et al.	424	461	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER			DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
										YES	NO		
	CA												
OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, Etc.)													
	CC	Crain et al., "Antagonists of excitatory opioid receptor functions enhance morphine's analgesic potency and attenuate opioid tolerance/dependence liability"; Dept. Of Neuroscience, Albert Einstein College of Medicine, Pain 82 (1999) pg. 1-11											
	CD	Crain et al., "Antagonists of excitatory opioid receptor functions enhance morphine's analgesic potency and attenuate opioid tolerance/dependence liability"; Dept. Of Neuroscience, Albert Einstein College of Medicine, Pain 84 (2000) pg. 121-131											
	CE	Fink, et al., "Naloxone in Heroin Dependence"; Clin Pharm and Therapeutics, Vol 9, No. 5, pg. 568-577											
	CF	Fishman, et al., "Disposition of Naloxone-7,8- ³ H in Normal & Narcotic-Dependent Men"; J. of Pharm. and Experimental Therapeutics (1973) Vol 187, No. 3, pg. 575-580											
	CC	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology 1, (1990) Vol 10, No. 2, pg. 375-386											
	CH	Freye, et al., "Effects of Tramadol and Tilidine/Naloxone on Oral-Caecal Transit & Pupillary Light Reflex"; Arzneimittel-Forsch/Drug Res. 50 (I) (2000) pg. 24-30											
	CI	Fudala, et al., "Effects of Buprenorphine and Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pg. 1-8											
	CJ	Fudala, et al., "Human Pharmacology and Abuse Potential of Nalmefene"; Clin Pharm and Ther (1991) Vol 49, 3, pg. 300-306											
	CA	Gal, et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharmacol Ther. (1986) pg. 537-542											
	CC	Gerra, et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pg. 35-41											
	CM	Ghosh, et al., "Opioid analgesics and narcotic antagonists"; Side Effects of Drugs (2000) Annual 23, Ch. 8, pg. 96-113											
	CN	Glatt, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol 17, No 3, pg. 193-197											
	CO	Gold, et al., "Rapid Opioid Detoxification during General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, 1639-1647											
	CP	Greenwald, et al., "Comparative Clinical Pharmacology of Short-Acting μ Opioids in Drug Abusers"; J. Pharm. and Experimental Therapeutics (1996) Vol 277, No 3, pg. 1228-1236											
EXAMINER /James Alstrum Acevedo/						DATE CONSIDERED 06/08/2008							
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/761,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER		DATE	NAME	CLASS	FILING DATE IF APPROPRIATE
	DB	4	9	4	0	9	8
					07/10/1990	Jenkins, et al.	424
						480	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER		DATE	COUNTRY	CLASS	SUBCLASS
							TRANSLATION
							YES
							NO
	DB						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	DC	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anaesthesia (1974) Vol 29 pg. 33-39					
	DD	Richter, et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arzneim-Forsch/Drug Res. 35 (No II) (1985) pg. 1742-1744					
	DK	Rosen, et al., "Effect of Clonidine Pretreatment on Naloxone-Precipitated Opiate Withdrawal"; J. of Pharm. and Experimental Ther. (1996) Vol 276, No 3, pg. 1128-1135					
	DF	Rosen, et al., "The effect of lamotrigine on naloxone-precipitated opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pg. 173-176					
	DG	Rosen, et al., "A pilot study of dextromethorphan in naloxone-precipitated opiate withdrawal"; European J. of Pharm. (1996) Vol 307, pg. 251-257					
	DK	Schuh, et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. of Pharm. and Experimental Ther. (1996) Vol 278, 2, pg. 836-846					
	DK	Schuh, et al., "Onset, magnitude and duration of opioid blockade produced by buprenorphine and naltrexone in humans"; Psychopharmacology (1999) Vol 145, pg. 162-174					
	DJ	Stevens, et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pg. 210-211					
	DK	Stine, et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug Alcohol Abuse (1994) Vol 20, (4), pg. 445-458					
	DC	Stine, et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. of Clinical Psych. (1992) Vol 12, No. 3, pg. 203-209					
	DM	Stoller, et al., "Effects of buprenorphine/naloxone in opioid-dependent humans"; Psychopharmacology (2001) Vol 154, pg. 230-242					
	DN	Strain, et al., "Acute effects of buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. of Pharm. and Experimental Ther. (1992) Vol 261, No. 3, pg. 985-993					
	DK	Strain, et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pg. 374-383					
	DK	Strain, et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. of Pharm. and Experimental Ther. (1993) Vol 267, No 2, pg. 624-634					
	DQ	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages					
	DK	Umbrecht, et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56, pg. 181-190					
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.		GROUP: 1615	
				FILING DATE: February 8, 2001			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	EA	0 0 7 0 0 7 0	11/13/1990	Oshlack	424	451	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	EB						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	EE	Vaccaro, et al., "Endogenous Opiates: 1999"; Peptides 21 (2000) pg. 1975-2034					
	ED	Wang, et al., "Inverse agonists and neutral antagonists at μ opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. of Neurochemistry (2001) Vol 77, pg. 1590-1600					
	EE	Way, et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pg. 252-261					
	EE	Weinberg, et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Ther (1988) Vol 44, No 3, pg. 335-342					
	EG	Wells, et al., "In Vivo Pharmacological Characterization of SRJ 9409, a Nonpeptidic Opioid μ -Agonists/ δ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper. Thera. (2001) Vol 297, No 2, pg. 597-605					
	EH	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pg. 4-6					
	EI	Wright, et al., "Acute physical dependence in humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pg. 139-148					
	EJ	Zhu, et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration of NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pg. 325-336					
	EK	Han, et al., "Mucoadhesive buccal disks for novel nalbuphine prodrug controlled delivery: effect of formulation variables on drug release and mucoadhesive performance"; International J. of Pharm (1999) Vol 177, pg. 201-209					
	EE	Handal, et al., "Naloxone"; Annals of Emergency Medicine (1983) Vol 12:7, pg. 438-445					
	EM	Harris, et al., "Buprenorphine and naloxone co-administration in opiate-dependent patients stabilized on sublingual buprenorphine"; Drug and Alcohol Dependence (2000) Vol 61, pg. 85-94					
	EN	Hawkes, et al., "Effect of an enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; Aliment Pharm Ther (2001) Vol 15, pg. 625-630					
	EO	Högger, et al., "Comparison of tilidine/naloxone, tramadol and bromfenac in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; International J. Clin Pharm and Ther (1999) Vol 37, No 8, pg. 377-385					
EXAMINER James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT													
(Use several sheets if necessary)													
				APPLICANT(S): Oshlack, et al.									
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
	FB	4	9	2	4	4	3	8	01/22/1991	Kreek, et al.	514	282	
	FB	4	9	9	2	3	4	4	02/05/1991	Goldie, et al.	424	484	
	FB	6	2	2	1	2	1	2	12/10/1991	Malkowska, et al.	424	497	
	FD	6	9	9	1	1	9	2	02/25/1992	Heafield, et al.	424	457	
	FE	6	2	1	5	2	9	8	06/01/1993	Krishnamurthy	424	493	
	FI	6	2	2	2	3	3	1	07/13/1993	Thompson, et al.	73	855.9	
	FG	6	2	6	6	3	3	1	11/30/1993	Oshlack, et al.	424	497	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
										YES NO			
	FI												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	FI	Budd, Keith, "Clinical use of Opioid Antagonists"; Bailliere's Clinical Anesthesiology (1967) Vol 1, No 4, pp. 993-1011											
	FJ	Crain, et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic cotreatment"; Proc. Natl. Acad. Sci (1995) Vol 92, pp. 10540-10544											
	FK	Howes, et al., "The Pharmacology of TR5109, a New Narcotic Agonist/Antagonist Analgesic"; NIDA Research (1979) pp. 99-105											
	FL	Leeling, et al., "Disposition and metabolism of codorphone in the rat, dog and man"; Drug Metabolism and Disposition (1982) Vol 10, No 6, pp. 649-653											
	FM	Amass, et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pp. 143-152											
	FN	Hussain, et al., "Buccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pp. 127-130											
	FO	Jasinski, et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. of Pharm and Exper Thera (1967) Vol 157, No. 2, pp. 420-426											
	FP	Jones, et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusing humans"; Drug and Alcohol Dependence (2000) Vol 60, pp. 29-37											
	FC	Kano, et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J. of Pharm and Exper Thera (1992) Vol 260, No. 1, pp. 355-363											
	FR	King, et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exp Res (1997) Vol 21, No. 5, pp. 906-909											
EXAMINER /James Alstrum Acevedo/							DATE CONSIDERED 06/08/2008						
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.									
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		DOCUMENT NUMBER			DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
	GA	5	2	8	8	4	9	3	02/15/1994	Oshlack, et al.	424	456	
	GF	5	3	2	1	3	5	1	06/28/1994	Oshlack, et al.	106	153	
	GF	5	3	1	6	8	9	1	08/09/1994	Raffa, et al.	514	629	
	GF	5	3	0	6	8	6	1	10/18/1994	Oshlack, et al.	106	153	
	GF	5	4	1	1	7	8	5	05/02/1995	Oshlack, et al.	424	456	
	GF	5	1	0	0	8	2	8	10/24/1995	Merrill, et al.	424	470	
	GG	5	1	7	2	7	1	2	12/05/1995	Oshlack, et al.	424	480	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER			DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
									YES	NO			
	GH	8	2	0	1	2	8	2	03/12/1987	WO	A61K	31/485	
	GF	8	1	8	2	7	8	0	05/10/2001	WO (A2)	A61K	31/485	
	GF	8	1	8	8	0	8	0	09/20/2001	WO (A2)	A61K	31/00	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	GK	Kogan, et al., "Estimation of the Systemic Availability and other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. in Chem. Path. and Pharm (1977) Vol 18, No. 1, pg. 29-34											
	GL	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J. of Psychiatry (1994) Vol 1, pg. 151											
	GM	Kosten, et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, pg. 73-78											
	GN	Kurland, et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No. 5, pg. 663-672											
	GM	Lee, et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1997) Vol 84, pg. 810-815											
	GP	Lehmann, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory Effects of Buprenorphine"; Eur J. Clin. Pharm. (1988) Vol 34, 343-352											
	GQ	Levine, et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J. Clin. Invest. (1988) Vol 82, pg. 1574 - 1577											
EXAMINER /James Alstrum Acevedo/						DATE CONSIDERED 06/08/2008							
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081								
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.										
				FILING DATE: February 8, 2001		GROUP: 1615								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	HA	5	6	7	8	5	2	2	12/26/1995	Sackler, et al.	424	489		
	HA	5	5	6	0	2	2	2	03/19/1996	Oshlack, et al.	424	489		
	HC	5	5	6	2	6	6	2	04/16/1996	Oshlack, et al.	424	468		
	HD	5	5	0	8	6	6	3	04/16/1996	Krishnamurthy	424	489		
	HF	5	5	0	6	0	6	2	08/27/1996	Oshlack, et al.	424	468		
	HF	5	5	5	2	0	2	2	09/03/1996	Gauthier, et al.	514	368		
	HG	5	5	6	1	6	5	2	01/07/1997	Miller, et al.	424	468		
	HH	5	6	6	1	6	6	5	02/11/1997	Buxton, et al.	424	468		
	HF	5	6	2	2	7	2	2	04/22/1997	Knott, et al.	424	494		
	HJ	5	6	3	0	4	2	6	06/17/1997	Oshlack, et al.	424	468		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	HK													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	HR	Loimer, et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy", J. of Substance Abuse Treatment (1991) Vol 8, pg. 157-160												
	HM	Martin, et al., "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation", Arzneim.-Forsch./Drug Res. (1999) Vol 49, pg. 599-607												
	HN	Martin, et al., "Demonstration of Tolerance to and Physical Dependence on N-allylnormorphine (Nalorphine)", J. of Pharm and Exper Thera (1965) Vol 150, No. 3, pg. 437-442												
	HO	Mendelson, et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine-stabilized, opiate-dependent volunteers", Psychopharmacology (1999) Vol 141, pg. 37-46												
	HM	Mendelson, et al., "Buprenorphine and Naloxone Interactions in Methadone Maintenance Patients", Society of Biological Psychiatry (1997) Vol 41, pg. 1095-1101												
	HO	Nutt, et al., "Methadone-naloxone mixtures for use in methadone maintenance programs", Clin Pharma and Thera, Vol 15, No. 2, pg. 156-166												
	HR	Parwatikar, et al., "Methadone-naloxone in combination for the treatment of heroin addicts", Clin Pharm and Thera, Vol 14, No. 6, pg. 941-948												
EXAMINER /James Alstrum Acevedo/										DATE CONSIDERED 06/08/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609, Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	IB	5 5 5 4 4 9 5	08/12/1997	Oshlack, et al.	424	468	
	IB	5 5 7 5 1 7 2	09/30/1997	Buxton, et al.	424	495	
	IC	5 5 7 2 5 5 0	09/30/1997	Sackler, et al.	424	490	
	ID	5 4 5 1 5 8 8	10/28/1997	Oshlack, et al.	424	494	
	IE	5 7 5 4 4 5 4	06/09/1998	Miller, et al.	514	282	
	IF	5 7 8 4 4 7 4	07/14/1998	Kim	514	282	
	IC	5 5 1 1 1 2 4	09/22/1998	Krishnamurthy	424	498	
	IH	5 4 5 5 4 7 4	11/10/1998	Mioduszewski	514	282	
	IH	5 4 5 4 5 4 0	12/01/1998	Miller, et al.	424	495	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	IH						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	IK	Parwattikar, et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pg. 1350-1354					
	IL	Pitts, et al., "Antinociceptive and Response Rate-Altering Effects of <i>Kappa</i> Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in combination with Opioid Antagonists in Squirrel Monkeys"; J. Pharm and Exper Thera (1994) Vol 271, No. 3, pg. 1501-1508					
	IM	Preston, et al., "Buprenorphine and Naloxone alone and in combination in opioid-dependent humans"; Psychopharmacology (1988) Vol 94, pg. 484-490					
	IN	Preston, et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J. Pharm and Exper Thera (1993) Vol 264, No. 2, pg. 813-823					
	IO	Preston, et al., "Effects of Sublingually given naloxone in opioid-dependent human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pg. 27-34					
	IK	Bigelow, et al., "Abuse Liability Assessment of Buprenorphine-Naloxone Combinations"; Dept. of Psychiatry and Behavioral Sciences - The Johns Hopkins University School of Medicine, pg. 145-149					
	IO	Wikler, et al., "N-Allylnormorphine: Effects of single doses and precipitation of acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post-addicts); N-Allylnormorphine During Narcotic Addiction (1953) pg. 8-20					
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT				APPLICANT(S): Oshlack, et al.		GROUP: 1615	
(Use several sheets if necessary)							
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
JF	5 5 4 5 1 4 4	12/15/1998	Miller, et al.	264	464		
JB	5 5 1 9 0 4 7	02/09/1999	Wong, et al.	424	473		
JD	5 5 4 5 1 4 5	04/06/1999	Heacfield, et al.	424	464		
JD	5 5 4 1 4 4 1	04/06/1999	Miller, et al.	424	464		
JD	5 5 0 5 1 4 5	04/06/1999	Miller, et al.	514	282		
JF	5 1 5 5 4 5 7	09/28/1999	Oshlack, et al.	424	457		
JG	5 5 1 3 4 5 5	09/28/1999	Chasin, et al.	424	490		
JI	5 5 5 5 1 6 1	10/12/1999	Oshlack, et al.	424	457		
JI	5 5 5 5 1 5 4	10/12/1999	Miller, et al.	424	468		
JI	5 5 6 5 5 5 1	12/15/1999	Oshlack, et al.	424	456		
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
JI							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
JF	Zaks, et al., "Naloxone Treatment of Opiate Dependence", JAMA (1971) Vol 215, No. 13, pg. 2108-2110						
JM	Barton, et al., "Intranasal Administration of Naloxone by Paramedics", Prehospital Emergency Care (2002) Vol 6, No. 1, pg. 54-58						
JN	Blachly, Paul, H., M.D., "Naloxone in Opiate Addiction", Current Psychiatric Therapies (1976) pg. 209-213						
JW	Bashaw, et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade", Inter J. of Clin Pharm and Thera (1995) Vol 33, No. 9, 524-529						
JP	Jasinski, D.R., "Assessment of the Abuse Potential of Morphinelike Drugs (Methods Used in Man)", Drug Addiction (1977) pg. 197-258						
JD	Johnson, et al., "Buprenorphine and Naloxone for Heroin Dependence", Substance Use Disorders (2000) pg. 519-526						
JR	Strain, et al., "Opioid antagonist effects of dezocine in opioid-dependent humans", Clin Pharm and Thera (1996) Vol 60, No. 2, pg. 206-217						
EXAMINER /James Alstrum Acevedo/			DATE CONSIDERED 06/08/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081									
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.		GROUP: 1615									
				FILING DATE: February 8, 2001											
U.S. PATENT DOCUMENTS															
*EXAMINER INITIAL	DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	KP	5	0	2	5	6	5	2	02/15/2000	Oshlack, et al.	424	476			
	KB	5	0	5	1	8	5	5	05/30/2000	Leslie, et al.	424	457			
	KC	5	0	7	2	1	1	2	06/20/2000	Malkowska, et al.	424	457			
	KD	5	5	2	2	5	3	1	06/20/2000	Oshlack, et al.	424	461			
	KE	6	1	5	3	2	1	8	08/15/2001	Simon	424	449			
	KF	5	3	5	3	2	5	8	08/15/2001	Chasin, et al.	424	459			
	KG	5	1	4	1	1	2	3	11/07/2000	Sackler, et al.	424	459			
	KH	5	1	1	3	1	2	8	11/07/2000	Heafield, et al.	424	459			
	KC	5	1	5	2	4	5	7	12/19/2000	Miller, et al.	424	457			
	KJ	5	2	1	0	2	1	1	04/03/2001	Oshlack, et al.	424	476			
	KP	5	2	5	5	8	8	2	07/03/2001	Miller, et al.	424	468			
	KL	5	2	5	1	5	5	5	07/17/2001	Oshlack, et al.	424	457			
	KM	5	2	5	1	1	5	5	09/25/2001	Oshlack, et al.	424	457			
FOREIGN PATENT DOCUMENTS															
	DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
													YES	NO	
	KN	5	5	3	7	2	8	5	05/31/2001	WO (A2)	A61K				
	KO	0	1	5	2	8	5	1	09/25/2001	WO (A1)	A61K	31/485			
	KP	0	1	8	5	2	5	2	11/15/2001	WO (A2)	A61K				
	KQ	0	1	5	3	8	5	2	12/13/2001	WO (A2)	A61K	31/00			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
KR	Preston, et al., "Abuse liability studies of opioid agonist-antagonists in humans", Drug and Alcohol Dependence (1991) Vol 28, pg. 49-52														
KS	Bremscheidt, et al., "Pharmacokinetics of Nortilidine and Naloxone after Administration of Tilidine/Naloxone Solution or Tilidine/Naloxone Sustained Release Tablets", Arzneim.-Forsch/Drug Res. (2000) Vol 50, pg. 1015-1022														
EXAMINER /James Alstrum Acevedo/										DATE CONSIDERED 06/08/2008					
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.															

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.									
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
*EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	LA	6	6	6	8	4	4	8	10/23/2001	Oshlack, et al.	424	408	
	LB	6	3	2	8	0	2	2	12/04/2001	Miller, et al.	424	468	
	LC	6	6	3	5	0	3	5	01/01/2002	Oshlack, et al.	424	400	
	LD	6	4	7	8	6	5	7	04/23/2002	Kaiko, et al.	424	400	
	LI	6	3	6	7	4	6	8	05/14/2002	Oshlack, et al.	424	480	
	LI	6	3	6	5	0	6	8	05/14/2002	Miller, et al.	424	464	
	LG	6	4	7	8	6	6	4	11/05/2002	Kaiko, et al.	424	400	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES	NO
	LI												
	LI												
	LI												
	LK												
	LI												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	LM												
	LN												
	LD												
	LC												
EXAMINER /James Alstrum Acevedo/									DATE CONSIDERED 06/03/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081		
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.		FILING DATE: February 8, 2001		
				GROUP: 1615				
U.S. PATENT DOCUMENTS								
*EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	5 9 9 8 4 1 4	12/99	Mitch et al.	514	210.15		
	AB	5 9 7 7 6 4	12/99	Foss	514	282		
	AC	5 9 8 8 4 7	12/99	Reder et al.	424	449		
	AD	5 9 4 2 7 4 1	2/99	Chasin et al.	424	426		
	AE	5 9 8 0 1 1 7	3/99	Hill	514	282		
	AE	5 9 8 5 1 5 4	2/99	Kuczynski et al.	424	472		
	AG	5 9 5 5 5 0	1/99	Demopoulos et al.	604	49		
	AE	5 9 8 8 0 1 7	1/99	Demopoulos et al.	604	890.1		
	AE	5 7 8 7 1 7 5	6/98	Crain et al.	514	282		
	AJ	5 9 1 1 7 5 0	6/98	Qin et al.	514	282		
	AI	5 9 7 4 6 1 7	4/97	Qin et al.	514	282		
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AE	19 6 5 1 5 5 1	6/98	DE	A61K	31/485		
	AM	29 7 1 6 7 0 4	2/97	DE	A61K	31/485		
	AN	4 3 7 8 4 0 8	2/99	DE	A61K	31/485	X	
	AE	2 7 2 2 0 1 1	11/72	DE	A61K	27/00		
	AE	9 1 1 1 1 1 7	2/99	EP	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
AQ	Abstract, Cancer Chemother Pharmacol (1998); 42(4):287-91.							
AE	Yuan et al., Drug and Alcohol Dependence (1998); 52:161-165.							
AS	Gan et al., "Opioid-Sparing Effects of a Low-Dose Infusion of Naloxone in Patient-Administered Morphine Sulfate," Anesthesiology (1997), 87(5):1075-1080.							
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/08/2006				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA	5 2 7 6 2 2 7	4/97	Khanna et al.	514	399	
	BA	5 5 6 3 4 8	12/96	Crain et al.	514	12	
	BL	5 5 6 0 6 7 6	12/96	Crain et al.	514	282	
	BD	5 5 2 8 7 2 5	11/96	Portoghese et al.	546	35	
	BL	5 5 7 4 2 2	11/96	Rose et al.	514	343	
	BF	5 5 5 6 2 3 6	9/96	Mayer et al.	514	25	
	BL	5 5 3 4 4 6 2	7/96	Aston et al.	514	608	
	BL	5 5 4 4 2 2 0	9/96	Weber et al.	514	249	
	BL	5 5 4 2 6 7 8	9/96	Crain et al.	514	282	
	BL	5 5 0 2 0 1 6	9/96	Mayer et al.	514	249	
	BK	5 5 8 6 3 6 2	8/98	Kitchell et al.	424	426	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	BL	0 5 2 2 4 8	4/95	EP	A61K	31/485	
	BM	0 3 2 3 6 4	1/90	EP	A61K	31/485	
	BN	0 2 0 2 6 2	12/86	EP	A61K	9/22	
	BD	2 5 3 2 4 2 0	8/98	WO	A61K	31/485	
	Be	5 6 3 6 6 7 6	8/98	WO	A61K	31/485	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BQ	Shen et al., "Ultra-Low Doses of Naltrexone or Etorphine Increase Morphine's Antinociceptive Potency and Attenuate Tolerance/Dependence in Mice," Brain Research (1997), 757:176-190.					
	BR	Yuan et al., Clinical Trials and Therapeutics (1997), 61:467-475.					
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081								
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.		GROUP: 1615								
				FILING DATE: February 8, 2001										
U.S. PATENT DOCUMENTS														
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CD	5	4	2	2	5	4	3	12/95	Crain et al.	514	12		
	CB	5	4	5	2	2	0	0	12/95	Portoghese et al.	546	35		
	CF	5	4	2	0	1	1	2	6/95	Zagon et al.	514	282		
	CD	0	0	7	6	0	0	2	10/94	Ockert	514	282		
	CE	5	0	5	0	0	0	0	10/94	Bihari et al.	514	282		
	CF	5	3	5	2	6	5	3	10/94	Mayer et al.	514	289		
	CF	5	3	5	2	5	0	0	10/94	Portoghese et al.	514	279		
	CF	5	3	2	1	0	1	2	6/94	Mayer et al.	514	25		
	CI	5	3	1	2	0	2	2	5/94	Borsodi et al.	514	282		
	CJ	5	3	1	5	2	5	5	5/94	Rose et al.	424	12		
	CK	5	2	2	3	2	6	0	12/93	Oshlack et al.	424	486		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CF	9	2	3	3	5	0	6	3/94	WO	A61K	9/22		
	CM	5	5	5	2	2	5	1	2/95	WO	A61K	31/485		
	CN	0	5	0	3	0	0	4	2/95	WO	A61K	31/485		
	CD	5	4	0	6	4	7	6	3/94	WO	A61K	31/46		
	CF	0	0	0	0	1	0	2	9/83	WO	A61K	9/22		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	CQ	Mendelson J., et al, "Buprenorphine and Naloxone Interactions in Opiate-Dependent Volunteers," Clin. Phar. Ther. (1996), 60:105-114.												
	CR	Walsh et al., "Effects of Naltrexone on Response to Intravenous Cocain, Hydromorphone and their Combination in Humans," (1996).												
EXAMINER James Alstrum Acevedo/										DATE CONSIDERED 06/08/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.		FILING DATE: February 8, 2001	
				GROUP: 1615			
U.S. PATENT DOCUMENTS							
*EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	DB	5 7 5 5 8 6 5	10/93	Askanazi et al.	514	282	
	DB	5 3 3 5 7 7 3	8/93	Lee et al.	424	449	
	DH	5 7 7 5 4 4 0	7/93	London et al.	514	535	
	DC	5 3 3 3 5 3 3	3/92	Granger et al.	424	449	
	DE	5 7 5 7 8 3 3	4/92	Goldberg	514	282	
	DH	5 0 5 5 7 7 5	3/92	Sinclair	424	449	
	DG	5 0 8 5 0 5 8	2/92	Sinclair et al.	514	282	
	DH	5 0 7 8 3 3 7	12/91	Mendelson et al.	514	282	
	DH	4 5 3 5 4 2 8	8/95	Lewis	514	282	
	DJ	4 8 5 0 3 8 0	12/89	Rzeszotarski et al.	514	282	
	DK	3 8 8 7 3 3 8	11/89	Sinclair	514	282	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	DH						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	DM	Chih-Cheng Chien, Neuroscience Letters 190 (1995), 137-139.					
	DN	Crain et al., "Ultra-Low Concentrations of Naloxone Selectively Antagonize Excitatory Effects of Morphine on Sensory Neurons, Thereby Increasing Its Antinociceptive Potency and Attenuating Tolerance/Dependence During Chronic Cotreatment," Proc. Natl. Acad. Sci. USA (1995), 92:10540-10544.					
	DO	Hanson, Analgesic, Antipyretic and Anti-Inflammatory Drugs in Remington's Science and Practice of Pharmacy (1995), 2:1207.					
	DP	Physician's Desk Reference 48 th Ed. (1994) Montvale, NJ, 2120-2121.					
	DQ	Foss et al., J. Clin Pharmacol (1993), 33:747-751.					
EXAMINER James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.		FILING DATE: February 8, 2001	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	EB	4 0 7 3 0 7 0	10/89	Fishman et al.	412	10	
	EB	4 0 0 4 7 8 4	3/88	Goldberg	514	282	
	EC	4 0 0 4 5 9 0	3/88	Oshlack et al.			
	EC	4 0 0 6 5 5 8	2/89	Wuest et al.	514	381	
	EH	4 8 0 0 5 4 8	2/89	Choi	514	464	
	EF	4 8 0 0 3 4 1	2/89	Chien et al.	424	448	
	EC	4 0 0 3 7 0 0	3/88	Pasternek	514	282	
	EH	4 7 0 5 0 0 0	11/88	Kreek et al.	514	282	
	EH	4 7 0 0 3 7 7	3/88	Kreek et al.	514	282	
	EJ	4 7 0 0 0 0 0	3/88	Rzesutarski et al.	514	282	
	EB	4 7 3 0 0 4 0	3/88	Portoghesi et al.	546	10	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	EH						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	EH	Holmes et al., Anesth. Analg. (1993), 77:1166-73.					
	EH	Miaskowski et al., Brain Research (1992), 596:41-45.					
	EO	Weinhold et al., "Buprenorphine Alone and In Combination with Naltrexone in Non-Dependent Humans," Drug and Alcohol Dependence (1992), 30:263-274.					
	EB	Cappel et al., Pharma. Bioch. & Behav. (1989), 34:425-427.					
	EO	Vaccarino et al., Pain (1989), 36:103-109.					
	EO	Gonzalez et al., "Naltrexone: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Efficacy in the Management of Opioid Dependence," Drugs (1988), 35:192-213.					
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/03/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.A.A./

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.		FILING DATE: February 8, 2001	
				GROUP: 1615			
U.S. PATENT DOCUMENTS							
*EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		FB 4 7 1 6 7 7 6	4/86	Goldberg	514	282	
		FB 9 6 6 1 9 9 7	4/87	Lewis et al.	514	282	
		FI 4 6 6 6 3 7 6	4/86	Pasternak	514	282	
		FC 4 6 6 7 9 3 6	4/86	Lewis et al.	514	282	
		FB 9 9 7 3 9 3 6	3/86	Chen et al.	604	286	
		FF 4 4 6 4 3 7 6	8/84	Hussain et al.	424	260	
		FG 9 4 6 7 9 3 3	8/84	Gordon et al.	424	260	
		FI 4 4 6 1 4 7 6	8/84	Ganti	424	260	
		FI 9 4 6 1 9 7 7	8/83	Portoghese et al.	424	260	
		FJ 4 4 7 6 7 8 6	11/79	Goldberg	424	260	
		FI 3 3 6 6 3 4 6	6/76	Pachter et al.	424	260	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
		FI					
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	FM	Sunshine, et al., "Analgesic Efficacy of Pentazocine Versus a Pentazocine-Naloxone Combination Following Oral Administration," Clin. J. Pain (1988), 4:35-40.					
	FI	Wang et al., "Crossover and Parallel Study of Oral Analgesics," J. clin. Pharmacol (1981), 21:162-168.					
	FC						
	FP						
	FQ						
	FR						
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis Wright et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINE R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	GB	9 5 7 5 5 5 9	4/75	Pachter et al.	424	260	
	GB	5 7 7 9 5 5 5	11/73	Pachter et al.	424	260	
	GC	3 5 7 5 5 5 7	7/72	Lachman et al.	424	260	
	GC	5 9 9 3 5 5 7	7/72	Lewenstein et al.	424	260	
	GE	5 9 9 7 5 5 2	7/67	Blumberg et al.	260	285	
	GF	3 7 7 5 5 5 9	11/56	Fromherz et al.	167	65	
	GI						
	GH						
	GI						
	GJ						
	GI						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	GI						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	GM						
	GN						
	GO						
	GP						
	GQ						
	GR						
	GS						
EXAMINER /James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. D.
200.1133

ET NO.:

SERIAL NO.: 09/781,081

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Curtis WRIGHT, et al

FILING DATE: February 8,
2001

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	2	2	8	8	6	3	05/08/01	Palermo et al.	514	282	
	AB	6	2	7	7	3	8	4	08/21/01	Kaiko et al.	424	400	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AC	WO	98	2	5	6	1	3	06/18/98	EPO	A61K	31/485	Abstract	
	AD	WO	00	3	8	6	4	9	07/06/00	EPO	A61K	9/00	Abstract	

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, Etc.)

AE	Press Release entitled "International Patent Application To Be Published on Abuse-Resistant Pain Reliever Being Developed by Purdue Pharma" August 8, 2001.
AF	Paronis, et al., Increased Analgesic Potency of Mu Agonists after Continuous Naloxone Infusion in Rats, J Pharm. Exper. Ther. 1991 259(2) pg 582-589
AG	Yoburn, et al., Supersensitivity to Opioid Analgesics Following Chronic Opioid Antagonist Treatment: Relationship to Receptor Selectivity, Pharmacol. Bio. Beh. 1995 51 (2) pg 535-539
AH	Crain, et al., Acute thermal hyperalgesia elicited by low-dose morphine in normal mice is blocked by ultra-low-dose naltrexone, unmasking potent opioid analgesia, Brain Res. 2001 888 pg 75-82
AI	Zhang, et al., Down-Regulation of μ -Opioid Receptors in Rat and Monkey Dorsal Root Ganglion Neurons and Spinal Cord After Peripheral Axotomy, Neuroscience 1998 82, pg 223-240
AJ	Abdulla, et al., Axotomy reduces the effect of analgesic opioids yet increases the effect of nociceptin on dorsal root ganglion neurons, J. Neuro Sci 1998 18, pg 9685-9694
AK	Di Giannuario, et al., Orphanin FQ reduces morphine-induced dopamine release in the nucleus accumbens: a microdialysis study in rats, Neurosci. Lett. 1999 272, pg 183-186
AL	Ciccocioppo, et al., Effect of nociceptin/orphanin FQ on the rewarding properties of morphine, Eur. J. Pharmacol. 2000 404, pg 153-159
AM	
AN	

EXAMINER

James Alstrum Acevedo/

06/08/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. //J.H.A./

11/4/2003

Sheet 1 of 1

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/761,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis WRIGHT, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AA	Bentley, Function of Myocardial α -ADRENOCEPTORS: Life Sciences (1982) Vol. 31 pg 101-112					
	AB	Levine, et al., Potentiation of Pentazocine Analgesia by Low-dose Naloxone J. Clin. Invest. (1988) Vol. 82 pg. 1574-1577					
	AC	Yoburn, et al., Opioid Antagonist-induced Receptor Upregulation: Effects of Concurrent Agonist Administration, (1994) (Publication Date): Brain Research Bulletin, Vol. 33 pg 237-240					
	AB	Bunzow, et al., Molecular cloning and tissue distribution of a putative member of the rat opioid receptor gene family that is not a μ , δ or κ opioid receptor type: FEBS Letters 347 (1994) pg. 284-288					
	AB	Mollereau, et al., ORL1, a novel member of the opioid receptor family: Cloning, functional expression and localization: FEBS Letters 341 (1994) pg. 33-38					
	AF	Wang, et al., cDNA cloning of an orphan opiate receptor gene family member and its splice variant: FEBS Letters 348 (1994) 75-79					
	AG	Suzuki, et al., Morphine conditioned place preference after chronic treatment with naloxone in the rat: Research Communications in Substances of Abuse. (1991) Vol. 12, No. 3 pg. 119-131					
EXAMINER James Alstrum Acevedo/				DATE CONSIDERED 06/08/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							